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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/766,889	01/19/2001	Rosalie Luiten	L0461/7104	9782

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EXAMINER
DIBRINO, MARIANNE NMN

ART UNIT	PAPER NUMBER
1644	

DATE MAILED: 07/29/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/766,889	LUITEN ET AL.	
	Examiner	Art Unit	
	DiBrino Marianne	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *5/12/03, 8/9/02 & 7/27/01* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3,5-9,31-34,48,50-53 and 67-70* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1, 3, 5-9, 31-34, 48, 50-53 and 67-70* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

1. Applicant's amendment's filed 7/27/01, 9/9/02 and 5/12/03 are acknowledged and have been entered.

2. Restriction to one of the following inventions is required under 35 U.S.C. § 121:

I. Claims 1 and 6, drawn to a method for diagnosing a disorder characterized by expression of MAGE-A1 peptide/HLA-B35 comprising use of a peptide/HLA-specific agent, classified in Class 435, subclass 7.1.

II. Claims 3 and 7, drawn to a method for diagnosing a disorder characterized by expression of MAGE-A1 peptide/HLA-B44 comprising use of a peptide/HLA-specific agent, classified in Class 435, subclass 7.1.

III. Claims 8 and 9, drawn to a method for enriching T lymphocytes specific for MAGE-1 peptide/HLA-B35 comprising use of an agent presenting the said MAGE-A1 peptide/HLA, classified in Class 435, subclass 7.2.

IV. Claims 8 and 9, drawn to a method for enriching T lymphocytes specific for MAGE-1 peptide/HLA-B44 comprising use of an agent presenting the said MAGE-A1 peptide/HLA, classified in Class 435, subclass 7.24.

V. Claims 31 and 32, drawn to an isolated T lymphocyte which binds to MAGE-A1 peptide/HLA-B35, classified in Class 435, subclass 325.

VI. Claims 31, 33 and 34, drawn to an isolated T lymphocyte which binds to MAGE-A1 peptide/HLA-B44, classified in Class 435, subclass 325.

VII. Claims 48, 50-53, drawn to a method for diagnosing a disorder characterized by expression of MAGE-A3 peptide/HLA-B35 comprising use of a peptide/HLA-specific agent, classified in Class 435, subclass 7.1.

VIII. Claims 67 and 68, drawn to an isolated T lymphocyte which binds to MAGE-A3 peptide/HLA-B35, classified in Class 435, subclass 325.

IX. Claims 69 and 70, drawn to an isolated APC which comprises MAGE-A3 peptide/HLA-B35, classified in Class 435, subclass 325.

3. Claim 5 links inventions I and II. The restriction requirement between the linked inventions is subject to the nonallowance of the linking claim, claim 5. Upon the allowance of the linking claim, the restriction requirement as to the linked inventions shall be withdrawn and any claim depending from or otherwise including all the limitations of the allowable linking claim will be entitled to examination in the instant application. Applicant are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim is presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

4. Invention (V and I) and Invention (V and III) are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. § 806.05(h)).

In the instant case, the product as claimed can be used in a materially different process such as immunopurification procedures.

5. Invention (VI and II) and Invention (VI and IV) are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. § 806.05(h)).

In the instant case, the product as claimed can be used in a materially different process such as diagnostic procedures.

6. Invention VIII and VII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. § 806.05(h)).

In the instant case, the product as claimed can be used in a materially different process such as immunopurification procedures.

7. Inventions (I-IV, VII) are different methods use.

These inventions require different ingredients and process steps to accomplish the use of either diagnosing a disorder (Inventions I, II and VII) or enriching T lymphocytes (Inventions III and IV). For example, Inventions I, III and VII involve use of an agent specific for HLA-B35 and a peptide restricted by HLA-B35, whereas Inventions II and IV involve use of an agent specific for HLA-B44 and a peptide restricted by HLA-B44. For example, the agents used in Inventions I-IV are specific for a MAGE-A1 derived peptide/HLA complex, whereas the agents used in Invention VII are specific for a MAGE-A3-derived peptide/HLA complex.

8. Inventions V, VI and VIII are different products.

The isolated T cells of Inventions V, VI and VIII are distinct because they are specific for complexes comprising different HLA molecules with different peptides and thus their modes of action are different.

Therefore they are patentably distinct.

9. Because these inventions are distinct for the reasons given above and the search required for any group from Groups I-VIII is not required for any other group from Groups I-VIII and Groups I-VIII have acquired a separate status in the art as shown by their different classification and divergent subject matter, restriction for examination purposes as indicated is proper.

11. This application contains claims directed to the following patentably distinct species of the claimed Inventions I, III, V: wherein the specificity of the agent in terms of the HLA/peptide complex (Inventions I and III) or the specificity of the isolated T lymphocyte (Invention V) is:

A) a MAGE-A1/ HLA-B35 binding peptide comprising SEQ ID NO: 10 and functional variants thereof;

B) a MAGE-A1/ HLA-B35 binding peptide consisting of a fragment of SEQ ID NO: 2 (that does not comprise SEQ ID NO: 10) and functional variants thereof;

These species are distinct because the structure of the peptide is different and thus the agent used in Inventions I, III or V and the T cell used in Invention V have different specificities.

Applicant is required under 35 U.S.C. § 121 to elect a single disclosed species (SEQ ID NO or portion thereof) for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

12. This application contains claims directed to the following patentably distinct species of the claimed Inventions II, IV, VI: wherein the specificity of the agent in terms of the HLA/peptide complex (Inventions II and IV) or the specificity of the isolated T lymphocyte (Invention VI) is:

A) a MAGE-A1/ HLA-B44 binding peptide comprising SEQ ID NO: 53 and functional variants thereof;

B) a MAGE-A1/ HLA-B44 binding peptide consisting of a fragment of SEQ ID NO: 2 (that does not comprise SEQ ID NO: 53) and functional variants thereof;

These species are distinct because the structure of the peptide is different and thus the agent used in Inventions II or IV and the T cell used in Invention VI have different specificities.

Applicant is required under 35 U.S.C. § 121 to elect a single disclosed species (SEQ ID NO or portion thereof) for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

13. This application contains claims directed to the following patentably distinct species of the claimed Inventions VII, VIII: wherein the specificity of the agent in terms of the HLA/peptide complex (Invention VII) or the specificity of the isolated T lymphocyte (Invention VIII) is:

A) a MAGE-A3/ HLA-B35 binding peptide comprising SEQ ID NO: 56 and functional variants thereof;

B) a MAGE-A3/ HLA-B35 binding peptide consisting of a fragment of SEQ ID NO: 55 (that does not comprise SEQ ID NO: 56) and functional variants thereof;

C) a MAGE-A3/ HLA-B35 binding peptide comprising SEQ ID NO: 59 and functional variants thereof;

These species are distinct because the structure of the peptide is different and thus the agent used in Invention VII and the T cell used in Invention VIII have different specificities.

Applicant is required under 35 U.S.C. § 121 to elect a single disclosed species (SEQ ID NO or portion thereof) for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

14. Applicant is advised that a response to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 C.F.R. § 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. M.P.E.P. § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. § 103 of the other invention.

15. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.

16. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(h).

17. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marianne DiBrino whose telephone number is 703-308-0061. The examiner can normally be reached on Monday and Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan, can be reached on (703) 308-3973. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.
Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

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Patent Examiner
Group 1640
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July 28, 2003

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